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Frank C. Eisenschenk, Ph.D., Patent Attorney

AMENDMENT UNDER 37 C.F.R. § 1.116
Patent Application
Docket No. TPI.2900C3XC2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Jonathan S. Lau
Art Unit	:	1623
Applicants	:	Mark Tawa, Orn Almarsson, Julius F. Remenar
Serial No.	:	10/747,742
Filed	:	December 29, 2003
Conf. No.	:	2066
For	:	Pharmaceutical Propylene Glycol Solvate Compositions

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

AMENDMENT UNDER 37 C.F.R. § 1.116

Sir:

Applicants request that the period for response be extended two months through and including December 29, 2009, the fees for which have been paid at the time this Amendment was filed.

In response to the Office Action dated July 29, 2009, please amend the above-identified patent application as follows:

In the Specification

Please substitute the following paragraph "Cross-Reference to Related Applications" paragraph on page 1 (previously amended on August 21, 2004):

This application claims the benefit of U.S. Provisional Application No. 60/486,713, filed July 11, 2003, U.S. Provisional Application No. 60/459,501, filed April 1, 2003, U.S. Provisional Application No. 60/456,608, filed March 21, 2003, U.S. Provisional Application No. 60/456,027, filed March 18, 2003, U.S. Provisional Application No. 60/441,335, filed January 21, 2003, and U.S. Provisional Application No. 60/437,516, filed December 30, 2002. The content of each of these applications is hereby incorporated by reference in its entirety.

~~This application is also a continuation-in-part of U.S. Application No. 10/601,092, filed June 20,2003, which claims the benefit of U.S. Provisional Application No. 60/390,881, filed June 21, 2002, U.S. Provisional Application No. 60/426,275, filed November 14, 2002, U.S. Provisional Application No. 60/427,086, filed November 15, 2002, U.S. Provisional Application No. 60/429,515, filed November 26, 2002, U.S. Provisional Application No. 60/437,516, filed December 30, 2002, and U.S. Provisional Application No. 60/456,027, filed March 18, 2003.~~

~~This application is also a continuation-in-part of PCT/US03/19574, filed June 20, 2003, which claims the benefit of U.S. Provisional Application No. 60/390,881, filed June 21, 2002, U.S. Provisional Application No. 60/426,275, filed November 14, 2002, U.S. Provisional Application No. 60/427,086, filed November 15, 2002, U.S. Provisional Application No. 60/429,515, filed November 26, 2002, U.S. Provisional Application No. 60/437,516, filed December 30, 2002, and U.S. Provisional Application No. 60/456,027, filed March 18, 2003.~~

~~This application is also a continuation-in-part of PCT/US03/41273, filed December 24, 2003 (filed on December 24, 2003, entitled "Pharmaceutical Compositions With Improved Dissolution" (Attorney Docket No. TPI-1700CXC2 PCT) by Tawa et al.), which is a continuation-in-part of U.S. Application No. 10/601,092, filed June 20, 2003, said U.S. Application No. 10/601,092 claims the benefit of U.S. Provisional Application No. 60/390,881, filed June 21, 2002, U.S. Provisional Application No. 60/426,275, filed November 14, 2002, U.S. Provisional Application No. 60/427,086, filed November 15, 2002, U.S. Provisional Application No. 60/429,515, filed November~~

~~26, 2002, U.S. Provisional Application No. 60/437,516, filed December 30, 2002, and U.S. Provisional Application No. 60/456,027, filed March 18, 2003. Said PCT/US03/41273 is also a continuation-in-part of PCT/US03/19574 filed June 20, 2003, which claims the benefit of U.S. Provisional Application No. 60/390,881, filed June 21, 2002, U.S. Provisional Application No. 60/426,275, filed November 14, 2002, U.S. Provisional Application No. 60/427,086, filed November 15, 2002, U.S. Provisional Application No. 60/429,515, filed November 26, 2002, U.S. Provisional Application No. 60/437,516, filed December 30, 2002, and U.S. Provisional Application No. 60/456,027, filed March 18, 2003. Said PCT/US03/41273 is a continuation-in-part of U.S. Application No. 10/660,202, filed September 11, 2003, which is a continuation-in-part of PCT/US03/27772, filed September 4, 2003, which is a continuation-in-part of 10/378,956, filed March 3, 2003, which claims the benefit of U.S. Provisional Application No. 60/360,768, filed March 1, 2002. Said PCT/US03/27772, filed September 4, 2003, claims the benefit of U.S. Provisional Application No. 60/451,213, filed February 28, 2003, U.S. Provisional Application No. 60/463,962, filed April 18, 2003, and U.S. Provisional Application No. 60/487,064, filed July 11, 2003. Said U.S. Application No. 10/660,202, filed September 11, 2003, is also a continuation-in-part of U.S. Application 10/637,829, filed August 8, 2003, which is a divisional of U.S. Application No. 10/295,995, filed November 18, 2002, which is a continuation of U.S. Application No. 10/232,589, filed September 3, 2002, which claims the benefit of U.S. Provisional Application No. 60/406,974, filed August 30, 2002, U.S. Provisional Application No. 60/380,288, filed May 15, 2002, and U.S. Provisional Application No. 60/356,764, filed February 15, 2002. Said U.S. Application No. 10/660,202, filed September 11, 2003, is also a continuation-in-part of U.S. Application 10/449,307, filed May 30, 2003, which claims the benefit of U.S. Provisional Application No. 60/463,962, filed April 18, 2003, U.S. Provisional Application No. 60/444,315, filed January 31, 2003, U.S. Provisional Application No. 60/439,282, filed January 10, 2003, and U.S. Provisional Application No. 60/384,152, filed May 31, 2002. Said U.S. Application No. 10/660,202, filed September 11, 2003, is also a continuation-in-part of U.S. Application 10/601,092, filed June 20, 2003. Said U.S. Application No. 10/660,202, filed September 11, 2003, also claims the benefit of U.S. Provisional Application No. 60/451,213, filed February 28, 2003, U.S. Provisional Application No. 60/463,962, filed April 18, 2003, and U.S. Provisional Application No.~~

60/487,064, filed July 11, 2003.

PCT/US03/41273, filed on December 24, 2003, entitled "Pharmaceutical Compositions With Improved Dissolution" (Attorney Docket No. TPI 1700CXC2 PCT) by Tawa et al., U.S. Provisional Application Serial Nos. 60/437,516 (filed December 30, 2002); 60/441,335 (filed January 21, 2003); 60/456,608 (filed March 21, 2003); 60/459,501 (filed April 1, 2003); and 60/486,713 (filed July 11, 2003) are hereby incorporated by reference in their entireties.

In the Claims

1-6 (canceled).

7 (currently amended). A pharmaceutical composition comprising an excipient and a form of a propylene glycol solvate of celecoxib selected from:

a) a propylene glycol solvate of celecoxib sodium trihydrate characterized by ~~a PXRD pattern~~ the PXRD pattern of Figure 19 or Figure 21, said propylene glycol solvate of celecoxib sodium trihydrate having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate~~comprising peaks expressed in terms of 2-theta angles, said PXRD pattern comprising:~~

~~i) any 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more peaks selected from peaks at 3.47, 6.97, 10.37, 13.97, 16.41, 19.45, 21.29, 22.69, 23.87 or 25.75 degrees; or~~

~~ii) any 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, or more peaks at 3.43, 6.95, 10.25, 13.95, 16.39, 17.39, 17.75, 18.21, 19.43, 21.21, 22.61 or 25.71 degrees; or~~

b) a propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern of Figure 2A, 2B, 2C or 2D, said propylene glycol solvate of a sodium salt of celecoxib having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol~~comprising peaks expressed in terms of 2-theta angles, said PXRD pattern comprising any 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 of the following peaks: 3.77, 7.57, 8.21, 11.33, 14.23, 16.13, 18.69, 20.65, 22.69 and 24.77 degrees;~~

~~c) a propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern that comprises a peak at 8.21 degrees 2-theta; or~~

~~d) a propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern that comprises a peak at 8.79 degrees 2-theta~~

~~and wherein said PXRD pattern is obtainable by a technique employing a rotating sample tube~~.

8-25 (canceled).

26 (currently amended). The composition according to claim 7, wherein said form is a propylene glycol solvate of celecoxib sodium trihydrate characterized by the PXRD pattern of Figure 19 or Figure 21 and having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate~~and the composition is characterized by a PXRD pattern comprising peaks expressed in terms of 2-theta angles, said PXRD pattern comprising any 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more peaks selected from peaks at 3.47, 6.97, 10.37, 13.97, 16.41, 19.45, 21.29, 22.69, 23.87 or 25.75 degrees~~.

27 (currently amended). The composition according to claim 7, wherein said form is a propylene glycol solvate of a sodium salt of celecoxib, said propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern of Figure 2A, 2B, 2C or 2D and having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol.~~and the composition is characterized by a PXRD pattern comprising peaks expressed in terms of 2-theta angles, said PXRD pattern comprising:~~

~~any 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 of the following peaks: 3.77, 7.57, 8.21, 11.33, 14.23, 16.13, 18.69, 20.65, 22.69 and 24.77 degrees~~

28 (currently amended). The composition according to ~~claim 7~~claim 27, wherein said form is a propylene glycol solvate of a sodium salt of celecoxib and said composition is characterized by the PXRD pattern of Figure 2A~~a PXRD pattern that comprises a peak at 8.21 degrees 2-theta~~.

29 (currently amended). The composition according to ~~claim 7~~claim 27, wherein said form is a propylene glycol solvate of a sodium salt of celecoxib and said composition is characterized by the PXRD pattern of Figure 2B~~a PXRD pattern that comprises a peak at 8.79 degrees 2-theta~~.

30-31 (canceled).

32 (currently amended). The composition according to ~~claim 7~~claim 27, wherein said form is a propylene glycol solvate of a sodium salt of celecoxib and said composition is characterized by the PXRD pattern of Figure 2C~~said form is a propylene glycol solvate of celecoxib sodium trihydrate and the composition is characterized by a PXRD pattern comprising peaks expressed in terms of 2-theta angles, said PXRD pattern comprising any 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, or more peaks at 3.43, 6.95, 10.25, 13.95, 16.39, 17.39, 17.75, 18.21, 19.43, 21.21, 22.61 or 25.71 degrees~~.

33 (new). The composition according to claim 26, wherein said form is a propylene glycol solvate of celecoxib sodium trihydrate characterized by the PXRD pattern of Figure 19 and having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate.

34 (new). The composition according to claim 26, wherein said form is a propylene glycol solvate of celecoxib sodium trihydrate characterized by the PXRD pattern of Figure 21 and having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate.

35 (new). The composition according to claim 27, wherein said form is a propylene glycol solvate of a sodium salt of celecoxib and said composition is characterized by the PXRD pattern of Figure 2D.

36 (new). A propylene glycol solvate of celecoxib selected from:

a) a propylene glycol solvate of celecoxib sodium trihydrate characterized by the PXRD pattern of Figure 19 or Figure 21, said propylene glycol solvate of celecoxib sodium trihydrate having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate; or

b) a propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern of Figure 2A, 2B, 2C or 2D, said propylene glycol solvate of a sodium salt of celecoxib having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol.

37 (new). The propylene glycol solvate according to claim 36, wherein said propylene glycol solvate is a propylene glycol solvate of celecoxib sodium trihydrate characterized by the PXRD pattern of Figure 19 and having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate.

38 (new). The propylene glycol solvate according to claim 36, wherein said propylene glycol solvate is a propylene glycol solvate of celecoxib sodium trihydrate characterized by the PXRD pattern of Figure 21 and having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate.

39 (new). The propylene glycol solvate according to claim 36, wherein said propylene glycol solvate is a propylene glycol solvate of a sodium salt of celecoxib, said propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern of Figure 2A, 2B, 2C or 2D and having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol.

40 (new). The propylene glycol solvate according to claim 36, wherein said propylene glycol solvate is a propylene glycol solvate of a sodium salt of celecoxib and said composition is characterized by the PXRD pattern of Figure 2A.

41 (new). The propylene glycol solvate according to claim 36, wherein said propylene glycol solvate is a propylene glycol solvate of a sodium salt of celecoxib and said composition is characterized by the PXRD pattern of Figure 2B.

42 (new). The propylene glycol solvate according to claim 36, wherein said propylene glycol solvate is a propylene glycol solvate of a sodium salt of celecoxib and said composition is characterized by the PXRD pattern of Figure 2C.

43 (new). The propylene glycol solvate according to claim 36, wherein said propylene glycol solvate is a propylene glycol solvate of a sodium salt of celecoxib and said composition is characterized by the PXRD pattern of Figure 2D.

44 (new). A propylene glycol solvate of celecoxib selected from:

a) a propylene glycol solvate of celecoxib sodium trihydrate characterized by a thermogravimetric analysis of Figure 18 or Figure 20, said propylene glycol solvate of celecoxib sodium trihydrate having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate; or

b) a propylene glycol solvate of a sodium salt of celecoxib characterized by a thermogravimetric analysis of Figure 1, said propylene glycol solvate of a sodium salt of celecoxib having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol.

45 (new). The propylene glycol solvate of celecoxib according to claim 44, wherein the form is a propylene glycol solvate of celecoxib sodium trihydrate characterized by a thermogravimetric analysis of Figure 18, said propylene glycol solvate of celecoxib sodium trihydrate having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate.

46 (new). The propylene glycol solvate of celecoxib according to claim 44, wherein the form is a propylene glycol solvate of celecoxib sodium trihydrate characterized by a thermogravimetric analysis of Figure 20, said propylene glycol solvate of celecoxib sodium trihydrate having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate.

47 (new). The propylene glycol solvate of celecoxib according to claim 44, wherein the form is a propylene glycol solvate of a sodium salt of celecoxib characterized by a thermogravimetric analysis of Figure 1, said propylene glycol solvate of a sodium salt of celecoxib having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol.

48 (new). A propylene glycol solvate of celecoxib sodium trihydrate having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol: 3 hydrate.

49 (new). A propylene glycol solvate of a sodium salt of celecoxib having a stoichiometric ratio of 1 celecoxib: 1 sodium: 1 propylene glycol.

Remarks

Claims 7, 26-29 and 32 are pending in the subject application. By this Amendment, Applicants have amended claims 7, 26-29 and 32 and added new claims 33-49. Support for the amendments and new claim can be found throughout the subject specification and in the claims as originally filed (see, for example, page 27, paragraph 2 and Examples 1 and 7 of the as-filed specification). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 7, 26-29, 32 and 33-49 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

By way of this amendment, Applicants have revised the claim of priority. Support for the language added in the last sentence of the priority claim can be found, for example, at page 1 of the originally filed application.

Applicants gratefully acknowledge the Examiner's withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Claims 7, 26-29 and 32 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of "a propylene glycol solvate of celecoxib sodium trihydrate characterized by a PXRD pattern" and "a propylene glycol solvate of a sodium salt of celecoxib characterized by a PXRD pattern" because the stoichiometric ratio of: (propylene glycol to celecoxib to sodium and 3 molecules of water); and the stoichiometric ratio of: (propylene glycol to celecoxib to sodium) is not defined. The Office Action indicates that in view of the recitation and the definition of a solvate as requiring ingredients in definite proportion, it is unclear what the scope of ratios for the propylene glycol solvate is intended to be embraced by the claim. Applicants have amended the claims in accordance with the suggestion of the Examiner and submit that this issue is now moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 7, 26-29 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action states that it is unclear what scope of stoichiometric ratios for the propylene glycol solvates is embraced by the claims. Applicants respectfully assert that

there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention; however, in the interest of advancing prosecution in this matter, the claims have been amended to recite the stoichiometric ratios of compounds in the solvate and reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

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